



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

JUL 17 2019

OFFICE OF MISSION SUPPORT

Patrick A. Walsh, CIH  
Safety, Health and Environmental Manager  
Denka Performance Elastomer LLC  
560 Highway 44  
LaPlace, LA 70068

RE: Request for Reconsideration (RFR #17002A) concerning Toxicological Review of Chloroprene

Dear Mr. Walsh:

Thank you for your submittal of supplemental information concerning the development of the PBPK Model supporting your request for reconsideration (RFR #17002A) submitted by Denka Performance Elastomer LLC (DPE) regarding the 2010 Integrated Risk Information System (IRIS) Toxicological Review of Chloroprene.

This response acknowledges EPA's receipt of the CD containing digital copies of the materials prepared by Ramboll U.S. Corporation and provided to the Office of Research and Development (ORD) by Robert Holden. These materials were submitted on DPE's behalf on May 31, 2019. I also acknowledge your subsequent presentation of these materials to our Agency's subject matter experts at Research Triangle Park on June 12, 2019. A summary of that stakeholder meeting has been posted on EPA's Internet site at <https://cfpub.epa.gov/ncea/iris2/events.cfm#stakeholderMeetings> under "*Meetings Requested by Specific Members of the Public*." I understand that this meeting was helpful in outlining how the model will be evaluated through the IRIS quality assurance process, reviewed through the Agency's external peer review process, and if appropriate, apply the model via the IRIS Update process.

At this juncture, I am pausing reconsideration of your Information Quality Guidelines (IQGs) request until after the peer review results regarding your submitted PBPK model have been fully assessed. EPA estimates it will take a minimum of nine months to complete the IRIS quality assurance and peer review processes. In accordance with EPA's IQGs, EPA will then review and assess the results of these reviews and convene an IQG Executive Panel to reconsider EPA's response to your original request for correction. Under EPA's IQGs, this Executive Panel will make the final decision on the RFR.

Alternatively, DPE may withdraw this RFR until after the peer review process has been completed, then resubmit it again at a later time. If you wish to withdraw the RFR, please let us know. EPA will plan to provide DPE with a status update on this RFR by December 30, 2019.

Sincerely,

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Vaughn Noga  
Deputy Assistant Administrator for Environmental Information  
And Chief Information Officer

cc:

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